CONFIDENTIAL K052619

JAN 6 2006

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name: The Finger Guard®

Common Name: Protective digit cover for use with oximeter sensor/probe

Classification Name: Accessory to reusable oximeter finger sensor/ probes

Regulation Number and Class: 870.2700; Class II

Product Code: DQA

Applicant: T F & G Products
6956 Oro Bangor Hwy.
Oroville, CA
9566-8249
Telephone: 530-679-0443

Contact Person: Mariruth Gurley

Intended Use: Single use, disposable digit cover for use as an accessory to a reusable pulse oximeter finger sensor/probe. The device may provide a minimum physical barrier protection from the digit on which the device will be used. To help prevent gross contamination of the pulse oximeter sensor/probe.

Device Description: The device is a tubular clear sheath/sleeve. It has an opening for insertion of a digit. The sleeve is placed on the digit, and the pulse oximeter sensor/probe is placed over the sleeve/sheath.

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Substantial Equivalence: The Finger Guard® is substantially equivalent to the predicate device Coverox Sheath, cleared under K 964821. The following provides a comparison of the new device to the predicate device.

Device	New Device	Predicate Device
	The Finger Guard®	Coverox Sheath Models Number PS65, PS 67 and EPS
Class	II	II
Intended Use	For use as an accessory to a reusable pulse oximeter finger tip sensor/probe to . It may provide a minimum barrier protection from the digit on which the device will be used. It may help prevent transfer of contamination to the probe.	For use in conjunction with a reusable pulse oximeter finger tip sensor/probe of the clothes pin style. It provides a gross contamination barrier between the finger and the probe. It prevents transfer of contamination to the probe.
Materials of construction	Clear low density polyethylene copolymer film.	Clear plastic; type or grade unknown.
Technical Characteristics	The Finger Guard® is a clear plastic sleeve placed directly on the finger. It is transparent and of such thickness as to allow the reading of the pulsation of the blood in the finger. After use the sleeve is removed and discarded.	The Coverox is a clear plastic sheath placed directly on the sensor/probe. It is transparent and of such a thickness as to allow the reading of the pulsation of the blood in the finger. After use the sheath is removed and discarded.
Product Labeling	Single use, non-sterile, latex free, powder free, disposable	Single use, non-sterile, disposable.

Discussion of similarities and differences

The new device and the predicate device are for the same intended use. They are both made of clear plastic. The duration of use of both devices is 15-20 seconds at any one time that a pulse oximeter reading is taken. Both devices are single use, non-sterile, and disposable.

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The technical difference between the devices is the placement of the protective sleeve/sheath. The new device is a plastic sleeve placed directly on the finger before the oximeter sensor/probe is placed on the finger. The predicate device is a plastic sheath placed on the oximeter finger sensor/probe itself before the probe is placed on the finger. This technological difference does not raise new issues of safety or effectiveness. The same type of material, i.e. plastic, comes into contact with the skin. Both protective covers allow the oximeter reading to be taken, while providing a physical barrier to gross contamination from the digit to the pulse oximeter probe/sensor. However, THE FINGER GUARD may provide a minimum barrier protection from the digit on which the device will be used. Based on this assessment, the new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 2006

Ms. Mariruth Gurley
President
T F & G Products
6956 Oro Bangor Highway
Oroville, California 95966-8249

Re: K052619
Trade/Device Name: The Finger Guard®
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 16, 2005
Received: December 19, 2005

Dear Ms. Gurley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONFIDENTIAL 18A

Statement of Indications for Use

510(k) Number: Not Known

Device Name: The Finger Guard®

Indications For Use:

The Finger Guard® is intended for use as an accessory to a pulse oximeter reusable finger sensor / probe. When the clear Guard is placed on a digit and the sensor / probe placed over the Guard, it may provide a minimum barrier protection between the digit upon which it is placed and the probe. It can be used anywhere a pulse oximeter is needed.

There is no other use for The Finger Guard®. If The Finger Guard® is used for any other purpose than stated above, it is used in that capacity without The Finger Guard® permission.

Prescription Use ___X___ AND /OR Over-The –Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 8-11 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General Hospital, Infection Control, Dental Devices

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NA 12/16/05